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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,998	04/20/2001	Philip A. Gale	045404.0002	3407

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AUSTIN, TX 78701

EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JLC

## Office Action Summary

Application No.

09/838,998

Applicant(s)

GALE ET AL.

Examiner

Rebecca L. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 118-140 is/are pending in the application.
- 4a) Of the above claim(s) 118, 119, 125, 126 and 131-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 120-124 and 127-130 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/20/01, 3/28/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

Claims 118-140 are currently pending in the instant application. Claims 118, 119, 125, 126 and 131-140 are withdrawn from consideration as being for non-elected subject matter. Claims 120-124 and 127-130 are rejected.

***Election/Restrictions***

Applicant's election with traverse of Group V and the further election of the composition of Structure I, in which  $n=4$ , all of the odd-numbered R groups are methyl, all of the even-numbered R groups are hydrogen, RA, RB, RC and RD are hydrogen, and the macrocycle is complexed to a chloride anion in the reply filed on 13 December 2004 is acknowledged. The traversal is on the ground(s) that the restriction requirement is late, and that it is improper since a search of the compounds of one group should result in any information and prior art related to the remaining groups. This is not found persuasive because 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action. In regards to the search, the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner. Accordingly, the requirement to restrict is considered proper and is maintained.

Therefore, as stated on page 5 of the restriction requirement: **The elected invention for search and examination is:** A composition comprising a calix[n]pyrrole macrocycle having the structure I (as seen in claim 121): wherein n is 4, p=q=r=s=0, R1-R16 are independently substituents as listed in i) below, and RA-RD are independently substituents as listed in ii) below;

i) hydrogen, halide, hydroxyl, alkyl, alkenyl or alkynyl;

ii) hydrogen or alkyl;

the macrocycle noncovalently-complexed to a halide anion.

The remaining subject matter of claims 120-124 and 127-130 that is not drawn to the above elected invention and the subject matter of claims 18, 119, 125, 126 and 131-140 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining compositions which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected composition and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the compositions comprising a calix[n]pyrrole macrocycle that has 5, 6, 7 or 8 pyrrole rings; wherein R1-R32 are aryl, alkylaryl, nitro, phosphor, formyl, acyl, hydroxyalkyl, alkoxy, hydroxyalkoxy, hydroxyalkenyl, a site-directing molecule, a catalytic group, a reporter group, etc.; wherein RA-RH are aminoalkyl, alkylsulfone, carboxyamidealkyl, N-oxide, etc.

The above mentioned withdrawn compositions which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and composition from the compositions of the elected invention. The compositions comprise

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macrocycles which are chemically recognized to differ in structure. Therefore, again, the compositions which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. These withdrawn compositions are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

### ***Claim Objections***

Claims 120-124 and 127-130 are objected to as containing non-elected subject matter. Claims 120-124 and 127-130 presented drawn solely to the elected invention identified above as: The elected invention for search and examination, and free of the following 35 USC 112 1<sup>st</sup> paragraph rejection would appear allowable over the prior art of record.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 120-124 and 127-130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions of the elected invention identified above in the section entitled: The elected invention for

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search and examination does not reasonably provide enablement for any composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, claims 120-124 and 127-130 are claiming compositions of the elected invention as identified above in the section entitled: The elected invention for search and examination. The state of the prior art is that a composition is a product of mixing or combining various elements or ingredients. While the level of the skill in the art is high, the lack of predictability in the art is that without guidance or direction as to what type of composition is being prepared, one of ordinary skill in the art would not know what elements or ingredients to combine or how to combine with the

calix[4]pyrrole macrocycle noncovalently-complexed to a halide anion in order to prepare the composition. It would require undue experimentation to prepare compositions other than pharmaceutical compositions, which are the only compositions that are provided in the instant specification, since there is no direction or guidance present as to what types of compositions can be prepared and how these compositions can be prepared except for pharmaceutical compositions. The only examples of compositions in applicants' instant specification is pharmaceutical compositions, see pages 40-42 which provides enablement only for pharmaceutical compositions by providing pharmaceutical acceptable carriers, modes of administration, and the treatment of body tissues. This rejection can be overcome by amending the claims to recite "pharmaceutical compositions" and including a pharmaceutically acceptable carrier.

### **Conclusion**


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
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